

CLAIMS

1. Method for the preparation of a vaccine composition comprising recombinant or
5 synthetic gelatin as a stabiliser, said method comprising the step of taking a
measure so that the water content remains below 2 wt.% in order to prevent the
recombinant gelatin from crystallisation during the lifetime of the composition.
2. Method according to claim 1 in which the recombinant gelatin is homodisperse.
3. Method according to claim 1 or 2 in which the molecular weight of the recombinant
10 gelatin is between 2.5 and 50 kD, preferably between 2.5 and 30 kD, and more
preferably between 2.5 and 15 kD.
4. Method according to any of the preceding claims in which the molecular weight of
the recombinant gelatin is between 5 and 10 kD, preferably between 6 and 8 kD.
5. Method according to any of the preceding claims, wherein the amino acid
15 sequences of said gelatin are essentially similar.
6. Method according to any of the preceding claims in which the lifetime is the time
from production to the moment of use of the composition.
7. Method according to any of the preceding claims in which the lifetime is the period of
storage of the composition.
- 20 8. Method according to any of the preceding claims in which the lifetime is at least 3
months, or at least 6 months, or at least one year or at least 2 years, or at least 7
years.
9. Method according to any of the preceding claims in which the measure that is taken
so that the water content remains below 2 wt.% is providing the composition in a
25 sufficiently moisture-tight container.
10. Method according to any of the preceding claims in which the measure that is taken
so that the water content remains below 2 wt.% is providing the composition in a
sufficiently air-tight container.
11. Vaccine composition comprising recombinant gelatin as a stabiliser, wherein said
30 composition has a water content of less than 2 wt.%.
12. Vaccine composition according to claim 11 which is at least 3 months old.
13. Method for the preparation of a vaccine composition comprising recombinant or
synthetic gelatin as a stabiliser, said method comprising the steps of (a) producing

recombinant or synthetic bi-modal or multi-modal gelatin, (b) adding said gelatin to a vaccine composition as stabiliser, and (c) lyophilizing said vaccine composition, whereby crystallisation of the recombinant gelatin is prevented during the lifetime of the composition.

- 5 14. Vaccine composition comprising recombinant or synthetic gelatin as a stabiliser, wherein said gelatin is bi-modal or multi-modal.
15. Vaccine composition according to claim 14, wherein the amino acid sequences of said gelatin are essentially similar.
- 10 16. Method for the preparation of a pharmaceutical composition comprising at least one therapeutic protein and further comprising recombinant or synthetic gelatin as a stabiliser, said method comprising the step of taking a measure so that the water content remains below 2 wt.% in order to prevent the recombinant gelatin from crystallisation during the lifetime of the composition.
- 15 17. Pharmaceutical composition comprising at least one therapeutic protein and further comprising recombinant or synthetic gelatin as a stabiliser, wherein said composition has a water content of less than 2 wt.%.